

**Abstract 105**

**TITLE:** Management Of Intravaginal Warts In HIV-Infected Women With A Dual Combination Therapy: 5-Fluorouracil (1%) In Injectable Hydrophilic Gel And Zidovudine 250 Mg.

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**OBJECTIVE:** The aim of this placebo-controlled, double-blinded study was to evaluate the clinical efficacy and tolerability of 5-Fluorouracil (1%) incorporated in a hydrophilic gel to cure intravaginal warts in HIV-infected women who were already on an oral regimen of Zidovudine (250 mg.), twice daily three times a week.

**METHODS:** Sixty female patients, aged between 18 to 50 years with confirmed HIV infection and having concurrent intravaginal warts (mean 5.3) entered the study. The diagnosis intravaginal warts was established by clinical, histopathological and Southern blot hybridization. Patients were sequentially assigned to receive a prepacked 40-ml. tube of trial preparation, and they self-administered the medication (4 ml.) deep into the vagina by an applicator once at bedtime every other day per week (1, 3 and 5). The study lasted for 16 weeks with 4 weeks of active treatment. Patients were examined on a weekly basis for 4 weeks and thereafter, were followed-up for 18 months on a monthly basis. Eradication of target lesions, absence of clinical signs of infection and Southern blot hybridization confirmed negative WV-DNA was recorded as treated.

**RESULTS:** By the end of the treatment findings indicated that 48.3% patients and 49.7% lesions were cured. Code disclosure revealed that 5-FU (1%) gel had cured 83.4% patients and 85.2% lesions. Placebo cleared 13.3% patients and 12.8% lesions;  $p < 0.0001$ . Thirteen patients 21.7% predominantly in the 5-FU gel group reported non-objective mild erythema, erosion and edema, with no dropout. Among cured patients four had a relapse after 14 months.

**CONCLUSION:** The study demonstrated that 5-Fluorouracil (1%) gel is tolerable, safe and significantly more effective than placebo to cure intravaginal warts in HIV-positive women, who were already on treatment with Zidovudine 250 mg. and the regimen can be considered as a reliable dual treatment modality to cure intravaginal warts.

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